

American Diabetes Association Policies and Procedures Related to Scientific Ethics and Integrity in Research Grants

The American Diabetes Association (ADA) adopted the following policies and procedures related to scientific ethics and integrity in grant proposals and awards on August 8, 2014.

Before a proposal will be considered by the Research Grant Review Committee, applicants must attest that 1) they have read and understand the information below; 2) the submitted work is original; and 3) the proposal is free of any form of scientific misconduct, as described below. Applicants can confirm their acceptance of these terms by checking the required box on the online proposal submission site.

This document describes:

- The most common forms of scientific misconduct, including the Association's specific policies and procedures related to plagiarism and image manipulation
- How the Association will investigate and respond to forms of scientific misconduct involving research grants and proposals
- How individuals can report concerns involving Association scientific programs

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Purpose and Scope

The mission of the American Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. To accomplish this mission, the Association funds research through its Core and Targeted Research Programs and the *Pathway to Stop Diabetes* initiative. In this context, scientific integrity refers to maintaining the quality and objectivity of research activities funded by the Association, such that they are sound and worthy of the public's confidence. In fostering scientific integrity, the Association aims to ensure that scientific findings are objective, credible and readily available to the public.

Submitted research projects should be well justified, well planned, and appropriately designed so that they can properly address the research objective of the study described in the application. Statistical issues, including power calculations, should be described to avoid futile studies that produce subject risk without enrollment sufficient to address the research objective. Outcomes should be specified at the start of the study. Research should be conducted to high standards of quality control and data analysis. Data and records, including the original versions of manuscripts, figures, and other files and supporting materials, must be retained by investigators for a period of 7 years and must be able to be produced for review, if requested. Fabrication, falsification, concealment, deceptive reporting, or misrepresentation of data constitutes scientific misconduct.

The Association expects investigators and institutions to follow the National Institutes of Health (NIH) guidelines on research conduct in "proposing, performing, or reviewing research, or in reporting research results" (U.S. Code of Federal Regulations, title 42, §93.103). The Sponsoring Institution is expected to have established procedures in place for addressing research misconduct, and is charged with fostering research integrity through enforcement of its institutional policies. Before a grant application is submitted to the Association, the Sponsoring Institution should ascertain and assure that submitted materials are the original work of the applicant and have not been used by other individuals in the preparation and submission of a similar grant application. The Principal Investigator (PI) must ensure the application has been routed through and approved by the usual administrative channels of the Sponsoring Institution prior to submitting the grant application to the Association. Electronic submission of the application effectively acknowledges that the institution has established relevant policies and procedures and agrees to abide by them while conducting research or other activities related to the Award.

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Definition of Research Misconduct

Public Health Service Policies on scientific misconduct are outlined as follows by U.S. Code of Federal Regulations 42 CFR Part 93:

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

A finding of research misconduct requires that—

- (a) There be a significant departure from accepted practices of the relevant research community; and
- (b) The misconduct be committed intentionally, knowingly, or recklessly; and
- (c) The allegation be proven by a preponderance of the evidence. ¹

Common Forms of Scientific Misconduct

The most common forms of scientific misconduct, with minor modification from "<u>Analysis of Institutional Policies for Responding to Allegations of Scientific Misconduct</u>" by the U.S. Department of Health and Human Services' Office of Research Integrity (ORI), are listed below.

- **Falsification of data:** ranging from fabrication to deceptive selective reporting of findings and omission of conflicting data, willful suppression and/or distortion of data, and inappropriate or fraudulent digital image manipulation. For more information about ADA's image manipulation policies, please see the section below.
- **Plagiarism:** The appropriation of the language, ideas, or thoughts of another and representation of them as one's own original work, or the duplication or re-use of one's previously published work without proper acknowledgment. For more information about plagiarism and how ADA detects for plagiarism, see the section below.
- Improprieties of authorship: Improper assignment of credit, such as excluding others,
 misrepresentation of the same material as original in more than one publication,
 inclusion of individuals as authors who have not made a definite contribution to the
 work published; or submission of multi-authored publications without the concurrence
 of all authors.

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¹ Public Health Service Policies on Research Misconduct, 42 CFR 93.103-104 (2005)

- Violation of generally accepted research practices: Serious deviation from accepted practices in proposing or carrying out research, improper manipulation of experiments to obtain biased results, deceptive statistical or analytical manipulations, or improper reporting of results.
- Material failure to comply with federal requirements affecting research: Including but not limited to serious or substantial, repeated, willful violations involving the use of funds, care of animals, human subjects, investigational drugs, recombinant products, new devices, or radioactive, biologic, or chemical materials.
- Inappropriate behavior in relation to misconduct: Including inappropriate accusation of misconduct; failure to report known or suspected misconduct; withholding or destruction of information relevant to a claim of misconduct and retaliation against person involved in the allegation or investigation.
- Deliberate misrepresentation of qualifications, experience, or research
 accomplishments to advance the research program, to obtain external funding, or for
 other professional advancement.
- Misappropriation of funds or resources. For example, misuse of funds for personal gain.

Automated Compliance Processing

The Association's plagiarism and image manipulation policies are further described below.

Plagiarism. Grant proposals submitted to Association Research Programs will be uploaded to CrossCheck/iThenticate, or equivalent plagiarism detection software, to scan the document for plagiarized text. As noted in the preceding section, plagiarism is scientific misconduct and will be addressed as such.

Association scientific programs have adopted the World Association of Medical Editors' definition of plagiarism: "Plagiarism is the use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source. The intent and effect of plagiarism is to mislead the reader as to the contributions of the plagiarizer. This applies whether the ideas or words are taken from abstracts, research grant applications, Institutional Review Board applications, or unpublished or published manuscripts in any publication format (print or electronic)."

"Self-plagiarism" refers to the practice of an author using portions of their previous writings on the same topic in another of his/her publications, without specifically and formally citing the previously published work. The Association will allow applicants to reuse *only* their own succinctly written literature reviews and brief descriptions of methodologies or patient characteristics from previously published work. Any reused methodology descriptions from previously published work should be properly cited.

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To avoid possible concerns or review delays, applicants should make a concerted effort to reword or rewrite text borrowed from the methodology descriptions of their own work. "Avoiding plagiarism, self-plagiarism, and other questionable writing practices," a resource developed by Miguel Roig, PhD, with funding from ORI, provides useful information on best practices related to ethical writing.

Digital Image Manipulation. The Association has adopted the statement first developed by the *Journal of Cell Biology* [J Cell Biol 166:11-15 (2004)] as its policy on the manipulation of digital images:

"No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. The grouping of images from different parts of the same gel, or from different gels, fields, or exposures must be made explicit by the arrangement of the figure (i.e., using dividing lines) and in the text of the figure legend. Adjustments of brightness, contrast, or color balance are acceptable if they are applied to the whole image [that is, every pixel] and as long as they do not obscure, eliminate, or misrepresent any information present in the original, including backgrounds. Without any background information, it is not possible to see exactly how much of the original gel is actually shown. Non-linear adjustments (e.g., changes to gamma settings) must be disclosed in the figure legend."

Digital images submitted with grant proposals may be scanned using image forensics software for any indication of improper manipulation. Cases of questionable or inappropriate image alterations will be referred to the Association's Panel on Ethical Scientific Programs (ESP). The ESP may request the original data from the applicant for comparison to the prepared figures. If the original data cannot be produced, the proposal will be rejected. Suspected cases of deliberate misrepresentation of data will be reported to the applicant's supervising institution or regulatory body.

For examples of what constitutes improper digital manipulation (as well as other forms of scientific misconduct), the Association encourages applicants to refer to the 2006 editorial by the *Journal of Clinical Investigation* titled "Stop Misbehaving!" [J Clin Invest 116:1740-1741 (2006)].

Applicants are also encouraged to refer to <u>Adobe's white paper</u> on using Photoshop in biomedical imaging. The paper provides useful information on maintaining image integrity, editing nondestructively, and the medical and scientific image workflow.

Responding to Allegations of Research or Scientific Misconduct

The American Diabetes Association's Panel on Ethical Scientific Programs (ESP) works on behalf of ADA scientific programs and publications, including the Research Grant Review Committee, to objectively and efficiently investigate cases of potential or perceived misconduct. The panel is comprised of expert independent investigators who share the Association's vision for appropriateness in scientific procedures.

The ESP takes seriously all reported concerns and allegations. When investigating and responding to cases of suspected misconduct, the panel operates with the utmost regard for the sensitivity, confidentiality, and impartiality required to fairly resolve each case. The ESP strives to keep the number of inquiries and those involved to the minimum necessary to reach a recommendation for responding to the allegation.

The panel will review the full documentary evidence available to assess the validity of the concerns or allegations, as well as the degree of possible misconduct. When necessary, the panel may consult with experts familiar with the topics, methods, or technical aspects presented in the proposal. In addition, ESP members may recuse themselves of the review of research or scientific misconduct cases for which they may have a personal or professional bias. In such cases, the Research Grant Review Committee will appoint an "ad hoc" expert to assist with the review. These experts will be blinded to the identities of the individuals when possible, and will be asked to agree to the Association's conflict-of-interest and confidentiality policies prior to consultation.

If the ESP determines through its initial review that the reported allegations or suspicions are of valid concern, the ESP will contact the applicant or author to notify him/her of the issue and to request an explanation and/or more information related to potential form of misconduct.

The ESP will review the applicant's response or explanation, the apparent degree of the particular or potential act of misconduct, and the apparent degree of the applicant's possible intent to deceive his/her audience.

If the ESP determines that the response and explanation are satisfactory, or that the reported issue is the result of honest error, then a letter of apology, explanation, and/or education (as deemed appropriate) will be sent to the person against whom the complaint is made. Where the misunderstanding appears to be not entirely innocent, a letter of reprimand, warning of the consequences of future such instances, will be sent to the same party.

If the ESP determines that the applicant's response and explanation are clearly unsatisfactory, the applicant admits guilt, or the applicant or his/her collaborators or co-authors do not respond to the panel's request for an explanation, the ESP will submit a written request to the applicant's supervising institution or regulatory body to carry out an investigation and to report the findings of the investigation in writing to the panel.

 On the basis of its review of the investigation report, the ESP will submit recommendations to the Review Grant Review Committee for how to respond to the allegation. If the inquiry concludes there is a reasonable possibility of misconduct, responses will be contingent on the apparent magnitude of the misconduct, the circumstances of the case, and the recommendations of the participating parties. The following responses have been modified from those listed by the <u>National Institutes of Health</u>, and may include, but are not limited to:

- Debarment from eligibility to receive ADA funds for grants and contracts
- Prohibition from service on ADA committees or advisory boards or as consultants
- Submission of a correction to or retraction of published articles by the respondent
- Modification of the terms of an ADA award, such as imposing special conditions or withdrawing approval of the principal investigator or other key personnel
- Suspension or termination of an award
- Recovery of funds
- Resolution of suspended awards.

Reporting Concerns Related to Research or Scientific Misconduct

Any individual may report concerns related to possible misconduct involving ADA scientific programs or publications by email to ESP@diabetes.org. Correspondents should provide as much information as possible to clearly describe the potential instances of misconduct, as well as the specific citation information or grant submission number, if available, for the work in question. Concerns will be referred to the Association's Panel on Ethical Scientific Programs for investigation. The ESP will only review concerns related to possible research and scientific misconduct, and will not review challenges to any decision regarding a submitted manuscript, abstract, or grant application.

Questions?

Please contact grantquestions@diabetes.org.